

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 60, 64-67, 71, 84, 87, 91-94, 98, 111, 143-158 and 159-173 are in the case.

I. ELECTION/RESTRICTION

The Examiner has noted that claims 74, 124 and 125 have been omitted from the list which read on the elected species. However, in view of the amendments presented with this response, claims 74, 124 and 125 have been cancelled without prejudice.

II. CLAIM OBJECTIONS

Claims 87 and 158 stand objected to for the reasons detailed in paragraph 2 on page 2 of the Action. In response, claims 87 and 158 have been amended to meet the Examiner's formal points. Withdrawal of the claim objections is now respectfully requested.

III. DOUBLE PATENTING

Certain claims stand rejected on obviousness-type double patenting grounds over claims of U.S. Patent 6,117,479 and U.S. Patent 6,406,738. In response, and without conceding to the merit of these rejections, in order to expedite prosecution, a Terminal Disclaimer is submitted herewith together with the requisite terminal disclaimer fee. Withdrawal of the outstanding obviousness-type double patenting rejections is now respectfully requested.

IV. THE ANTICIPATION REJECTIONS

Claims 60, 78, 83, 87, 105, 110, 114, 115, 116, 134 and 139 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent, 5,714,007 to Pletcher et al. Claims 60, 78, 83, 87, 105, 110, 111, 114, 115, 116, 134 and 139-140 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 5,846,595 to Sun et al.

In response to the rejection over Pletcher et al., that patent has a 35 USC 102(e) date of June 6 1995, which is subsequent to the British priority application 9509347.2 for this application filed on May 9, 1995 (a copy of this priority document should be in the USPTO file for this case). Attention is drawn to page 1, first paragraph, of the priority document, which mentions electrostatic coating with powder, and discloses the coating of an electrically insulating substrate, and specifically highlights the coating of a pharmaceutical tablet core. Attention is also directed to page 3, third complete paragraph, which clearly contemplates the use of biologically active material in the coating material to produce "a coated pharmaceutical".

Referring to the rejection over Sun et al., that patent is dated April 9, 1996, which is after the above first British priority application. It is also subsequent to the second British priority application 9520302.2 of October 5, 1995 (a copy of which should also be in the USPTO file). Page 1, first paragraph (including lines 11-17), page 25 lines 10-13 and claim 35 plus page 26 lines 6-9 of the second priority application are relevant to support. The latter disclosure refers to the application of "a dose", and it is inherent in this disclosure that the resulting product will be a unit dose.

Based on the above, it is believed that the currently pending claims are entitled to an effective date prior to that of the cited art. The invention as now claimed in the present application is therefore not anticipated by Pletcher or Sun. Reconsideration and withdrawal of the outstanding anticipation rejections based on those two references are accordingly respectfully requested.

V. THE OBVIOUSNESS REJECTIONS

Claims 79, 82, 86, 106, 109, 113, 135, 138, 142 and 153 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Pletcher or Sun. Claims 64-71, 73-76, 91-98, 100-103, 120-127, 129-132, 143-144, 149-150, 154-155 and 157-158 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Sun. Claims 63, 77, 80, 81, 85, 90, 104, 107, 108, 112, 119, 133, 136, 137, 141, 148, 151, 152 and 156 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Pletcher or Sun in view of WO 92/14451 to Staniforth. Those rejections are respectfully traversed.

Claims 79, 82, 86, 106, 109, 113, 135, 138 and 142 have been deleted without prejudice. The rejection of those claims has accordingly been rendered moot.

With regard to claims 64 to 67 and 91 to 94, the subject matter of those claims is entitled to the priority date of the second British priority application 9520302.5, dated October 5, 1995. For the specific features of those claims, attention is drawn to that priority document, page 9 lines 20-22, page 10, lines 15-20, page 11, lines 14-16, and page 26 lines 18-23, in conjunction with page 29, lines 9-12 (and see also claims 7 and 32 of that priority application in conjunction with the page 29 disclosure). For the

features of claims 60 and 87, on which the present claims 64-67 and 91-94 are based, the Examiner is directed to the comments presented above.

With regard to claims 71 and 98, the Examiner asserts that Sun et al discloses that some powders may comprise more than one active ingredient, and his position is that some of these powders will coalesce into composite particles. However, if different powders are simply mixed/blended there will not normally be formation of composite particles, although page 5 lines 26 to 32 of the present application states that composite particles may be obtained *in special cases by careful selection of the blending conditions and including selection of appropriate particle sizes of the initial components*. Normally, however, mere admixture does not result in composites. Therefore, unless there is a specific direction given (and there is no such disclosure in Sun et al), there is no disclosure of the formation of such particles. The present applicants have found that the use of composite particles, formed for example by the co-processing methods mentioned on page 5 lines 17 to 19 of the present specification, gives rise to improved efficiency in coating (see page 4 lines 14 to 28 of the present application and pages 15-16 of the second priority application). There is no disclosure or suggestion of this in Sun et al.

Claim 84 is not specifically mentioned as rejected under any of paragraphs 6 – 14. Claim 111, which is directed to the same feature, is rejected in paragraph 8 as allegedly anticipated by Sun et al. Attention is directed in this regard to the second British priority application, page 5, lines 12 to 15, for a disclosure of this feature, and to the comments above as to the earlier date of that application in relation to Sun et al.

With regard to claim 143, that claim specifies that the powder material used includes composite particles, and two alternative structures are mentioned (compare the features of claims 71 and 72). Since claim 72 is cancelled without prejudice, the composites listed in claim 143 have been amended to recite discrete composite particles (cf. claim 71).

As urged above in relation to claims 71 and 98, it is believed that there is no disclosure or suggestion in Sun et al. of the composite powder feature of claim 143. Withdrawal of the rejection of that claim together with the rejection of dependent claims 144 – 158 is accordingly respectfully requested.

Based on the above, it is clear that one of ordinary skill would not have been motivated to arrive at the presently claimed invention based on the disclosures of the references relied upon in the outstanding obviousness rejections. Absent any such motivation, a *prima facie* case of obvious has not been generated in this case. Reconsideration and withdrawal of the outstanding obviousness rejections are accordingly respectfully requested.

VI. NEW CLAIMS

New claims 159 and 160, dependent, respectively, on claims 60 and 87 (discussed above), contain the feature that, after coating, the powder coating material is fused. That feature is based on numerous references in the present specification to the fusibility of the powder coating, and is found in the first British priority application dated May 9, 1995 (see for example page 2, 4th complete paragraph, lines 3 to 5). It is therefore submitted that the claims have an earlier date than either of the cited patents.

New claims 161 and 162, dependent, respectively, on claims 60 and 87 (discussed above), contain the feature that the powder material contains two different components which have been co-processed. That feature is found on page 5 lines 17ff and page 24 lines 33-37 of the present specification and is found in the second British priority application dated May 9, 1995 (see for example page 15 line 21 to page 16, line 12). It is therefore believed that the claims have a date earlier than the date of Sun et al. It is further believed that Pletcher et al is not relevant here as there is no disclosure or suggestion in that specification to use two different materials in the coating. It is noted that the Examiner has not cited Pletcher et al against the present related claim 143.

New claim 163 is an independent claim containing the above feature discussed in relation to claims 161 and 162. The same comments apply in relation to Sun et al and Pletcher et al.

New claim 164, dependent on claim 163, contains the feature that the quantity of coating material applied constitutes one dosage of active material. That feature is inherent in the disclosure in the second British priority application, page 25 lines 13 to 17, that the coating material containing active material may be applied to a core containing no active material. The same comments as in the previous two paragraphs above apply in relation to the date of Sun et al and the non-relevance of Pletcher et al to a claim which, by its dependency, has the feature of claim 163.

New claims 165 – 171 contain the features of claims 64 – 67, 71, 84 and 159 discussed above, and are all dependent on claim 164 discussed above. The comments above apply. More especially, since Pletcher et al is not relevant and since Sun et al

does not disclose or suggest the features of claim 163, the above dependent claims, dependent indirectly on claim 163, are neither anticipated nor rendered obvious.

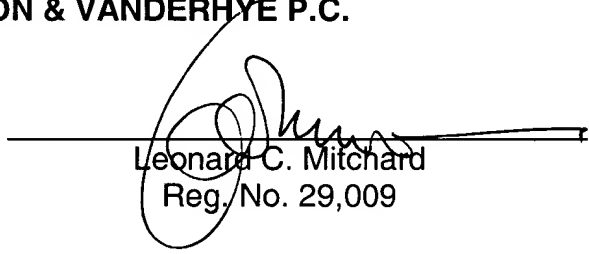
New claims 172 and 173, dependent on claims 143 and 164, respectively, contain the feature that the substrate contains a different active material from the powder material. That feature is found on page 18 lines 32 to 35 of the present specification. Since claims 172 and 173 are dependent on claims which are neither anticipated nor rendered obvious by the cited art, those citations are not relevant with respect to the dependent claims.

It is believed that the present application is now allowable condition. Favorable action in that regard is awaited.

Respectfully submitted,

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